

Notice of Allowability

Application No.

09/164,862

Examiner

Susan Ungar

Applicant(s)

PRICE ET AL.

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☐ This communication is responsive to November 17, 2006 and Interview of 1/26, 2007.
2. ☐ The allowed claim(s) is/are 1-8, 10, 13-18, 38, 39, 47, 49, 57-62 and 64, now renumbered 1-26, respectively.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit
of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☒ Interview Summary (PTO-413),
Paper No./Mail Date _____
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____

Susan Ungar
Primary Examiner
Art Unit: 1642

1. An Examiner's Amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 C.F.R. § 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the Issue Fee.

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 17, 2006 is acknowledged and has been entered. Claims 1, 38 and 47 have been amended. An action on the RCE follows.

3. Claims 1-18, 38-39, 47, 49, 56-67 are pending and currently under examination.

4. The application has been amended as follows:

In the claims:

Claim 1 was amended as follows and replaced with the following:

--Claim 1 (Currently amended): A method for estimating survival expectancy of a cancer patient, said method comprising:

(a) obtaining a biological fluid sample comprising human YKL-40 from a cancer patient having at least a preliminary diagnosis of a cancer, wherein the sample is collected either prior to surgery for the cancer or at the time of first recurrence of the cancer, selected from the group consisting of a lung cancer, a bronchus cancer, a colorectal cancer, a prostate cancer, a pancreas cancer, a stomach cancer, an ovarian cancer, a urinary bladder cancer, a brain or ~~central nervous system cancer, a peripheral nervous system cancer~~, an esophageal cancer, a cervical cancer, a melanoma, a uterine or endometrial cancer, a cancer of the oral cavity or pharynx, a liver cancer, a kidney cancer, a biliary tract cancer, a small bowel or appendix cancer, a salivary gland cancer, a thyroid gland cancer, an adrenal gland cancer, ~~an osteosarcoma, a chondrosarcoma, a liposarcoma~~, a testes cancer, and ~~a malignant fibrous histiocytoma~~; and

(b) measuring the level of said YKL-40 in said sample and comparing the sample YKL-40 level to the YKL-40 level found in the same sample from normal healthy humans wherein a sample YKL-40 level above 95% of the ~~greater than the~~ YKL-40 levels in the same sample from said normal healthy humans ~~at a confidence level of 95% or greater~~ is an indicator of a reduced survival expectancy compared to patients with normal YKL-40 level.--

Claim 10 was amended as follows: after “pleural effusion,” the phrase “urine, and tumor tissue” was deleted and the phrase --and urine-- was substituted.

Claim 38 was amended as follows: in section (a) after “fluid sample comprising” the term -- human-- was inserted.

Claim 38 was amended as follows: in section (a) after “bronchus cancer” the phrase “a colorectal cancer” was deleted.

Claim 38 was amended as follows: in section (b) after “wherein a sample YKL-40 level” the phrase “greater than the” was deleted and the phrase --above 95% of the—was substituted.

Claim 38 was amended as follows: in section (b) after “in normal controls” the phrase “at a confidence level of 95% or greater” was deleted.

Claim 47 was amended as follows: in the preamble of the claim the term “mammal” was deleted and the term -- human -- was substituted.

Claim 47 was amended as follows: in section (a) after “YKL-40 from said” the term “mammal was deleted and the term -- human -- was substituted.

Claim 47 was amended as follows: in section (b) line 2 after “from normal healthy” and line 4 after “normal healthy” the term “mammals” was deleted and the term -- humans -- was substituted.

Claim 47 was amended as follows: in section (b) after “wherein elevation in YKL-40” the phrase “at a confidence of 95% or greater” was deleted and the term --level-- was substituted.

Claim 47 was amended as follows: in section (b) after “being tested” the phrase “compared to the sample from” was deleted and the phrase --above 95% of the-- was substituted.

Claims 9, 11, 12, 56, 63, 65-67 were canceled.

5. Authorization for this Examiner's Amendment was given in a telephone interview with Tom Hunter on January 26, 2007.

6. Any comments considered necessary by applicant must be submitted no later than the payment of the Issue Fee and, to avoid processing delays, should preferably **accompany** the Issue Fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (703) 305-2181. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

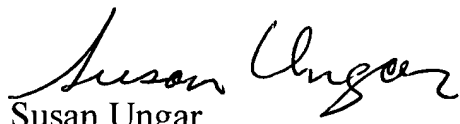
7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is

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(571) 272-0837. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley, can be reached at 571-272-0898. The fax phone number for this Art Unit is (571) 273-8300.

A handwritten signature in black ink, appearing to read "Susan Ungar". The signature is fluid and cursive, with the first name "Susan" and last name "Ungar" clearly distinguishable.

Susan Ungar
Primary Patent Examiner
February 1, 2007